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DATE: 10/12/17

IRO CASE #: XXXXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Right Shoulder Arthroscopy with Rotator Cuff Repair, Decompression Biceps Tenotomy Vs Tenodesis: 29826, 29827, 29823, 29828

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The reviewer is certified by The American Board of Orthopedic Surgery with over 10 years of experience.

REVIEW OUTCOME:
Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
Claimant is a XX injured on XXXX, while walking XX, fell on his right saide and now complains of right shoulder pain.

XXXX: MRI Right Shoulder. Impression- 1. Full-thickness tears of the supraspinatus and ifraspinatus tendons with 3.9 cm medial retraction and associated muscular fatty atrophy. Torn superior fibers of the subscapularis tendon with corresponding muscular atrophy. 2. Medial subluxation of the long head of the biceps tendon that is commonly seen with superior subscapularis tears. 3. Mild to moderate acromiovicular osteoarthritis. Small subacromial spur.

XXXX: Chart Note by Dr. XX. Pt sustained injury at work after XX. Pt fell with his arms outstretched. He immediately felt a severe pain in his rt shoulder. He is unable to lift his arm. He went to an XX and initially, x-rays were obtained. I reviewed 3 images; there was some AC joint DJD. No fractures or dislocations are seen. The pain persisted. He eventually had an MRI. He has been having 8/10 intensity pain with motion. He has 2/10 intensity pain at rest. He has noted weakness. He has pain at night, which does keep him awake. He has active elevation of the scapular plane of 80 degrees. Passive elevation is full. External rotation in 250 degrees. Internal rotation is to T10. He has 3/5 supraspinatus and infraspinatus strength testing. He has 4+/5 subscapularis strength testing. There is tenderness to palpitation in the bicipital groove only. There is positive Speed's and negative crossover. There is a negative apprehension. Cervical spine, he has good range of motion without pain. He would like to proceed with right shoulder arthroscopy with decompression, arthroscopic versus open rotator cuff repair, and possible repair of the subscapularis tendon, biceps tenotomy versus tenodesis. We will plan on scheduling as an outpatient procedure under general anesthesia.

XXXX: UR by Dr. XX. Rationale- Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. The provision of XX-XX months conservative treatments toward gaining full ROM was not yet completed, given the date of injury. Exceptional

factors were not identified as well.

XXXX: Chart Note by Dr. XX. I spoke with the physician reviewer for his case as it is a work comp case. I provided information regarding his conservative treatment. The pt has not had conservative treatment, as he has a full thickness tear. Knowing the activity level of the patient and the fact that it is his right arm, Dr. XX decided to appeal for a surgery without spending the time for conservative options. The pt is having persistent pain, disability, and inability to perform activities of daily living. He feels unsafe at work. He works XX. He at times has to XX them. He is having to do so primarily with the use of his contralateral upper extremity and feels as though this is hazardous. His pain level is moderate to severe. He requests pain medications. His pain is located deep in his shoulder. It is weak and he has limited motion. He has limited ROM. He forward flexes to 80 degrees, abducts to 80 degrees, and externally rotates to neutral, internal rotation to his gluteus. There is 3/5 strength with testing of the supraspinatus and infraspinatus. His subscapularis has 5/5 strength. There is tenderness to palpation over the anterior aspect of his shoulder. There is also some lateral tenderness. He has passive rom that is greater than active rom. He has positive impingement signs. Impression- 1. Full-thickness retracted right should supraspinatus and infraspinatus tendon tears. 2. Partial-thickness subscapularis tendon tear. 3. Biceps tendon subluxation. Rx for PT for 6 weeks. Pt was given a steroid injection of the right shoulder. Prescribed Tylenol #3. If PT fails, I will recommend surgery.

XXXX UR by Dr. XX. Rationale- The provision of XX-XX months conservative treatments toward gaining full ROM is not yet completed. The present findings are still insufficient to indicate a deficit in the rotator cuff and impingement of significant changes in the rt shoulder to justify the need for the requested surgeries. The significant functional limitation was still not clearly identified to further necessitate the request. Exceptional factors were not identified as well. Furthermore, after speaking the PA XXXXX, he confirmed the doctor, with full-thickness tears does not do conservative treatment to include PT and injections. The pt does not meet ODG criteria.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The previous adverse decisions are upheld. This patient injured his right shoulder at work in XXXX. His shoulder MRI demonstrates a large rotator cuff tear with associated fat atrophy, medial subluxation of the biceps tendon, and mild to moderate acromioclavicular osteoarthritis. On examination, he has limited active shoulder motion with associated weakness. He was prescribed 6 weeks of physical therapy and received a steroid injection to the shoulder. The Official Disability Guidelines (ODG) supports rotator cuff repair in patients with subjective and objective clinical findings that are consistent with a rotator cuff tear identified on imaging studies. This patient has a large rotator cuff tear with associated muscular fatty atrophy. The fatty atrophy points towards a chronic rotator cuff tear, which may have been aggravated by the recent fall. This patient should complete 3-6 months of physical therapy before considering shoulder surgery to repair the rotator cuff. This patient is not a surgical candidate at this point in time. Therefore, the request for right shoulder arthroscopy with rotator cuff repair, decompression, biceps tenotomy versus tenodesis is considered not medically necessary.

PER ODG…..
Recommended as indicated below.

See also Surgery for impingement syndrome; Continuous passive motion (CPM); Stem cell autologous transplantation .

ODG Indications for Surgery™ -- Rotator cuff repair:
Criteria for rotator cuff repair with diagnosis of moderate to large full-thickness rotator cuff tear AND cervical pathology and frozen shoulder syndrome have been ruled out:
1. Subjective Clinical Findings: Shoulder pain and inability to elevate the arm; tenderness over the greater tuberosity is common in acute cases. PLUS
2. Objective Clinical Findings: Patient may have weakness with abduction testing. May also demonstrate atrophy of shoulder musculature. Usually has full passive range of motion. PLUS

3. Imaging Clinical Findings: Conventional x-rays, AP, and true lateral or axillary views. AND MRI, ultrasound, or arthrogram shows positive evidence of deficit in rotator cuff.

Criteria for rotator cuff repair AND/OR anterior acromioplasty with diagnosis of small full-thickness or partial-thickness rotator cuff tear OR acromial impingement syndrome (80% of these patients will get better without surgery.)
1. Conservative Care: Recommend 3 to 6 months: Three months is adequate if treatment has been continuous, six months if treatment has been intermittent. Treatment must be directed toward gaining full ROM, which requires both stretching and strengthening to balance the musculature. PLUS
2. Subjective Clinical Findings: Pain with active arc motion 90 to 130 degrees. AND Pain at night (Tenderness over the greater tuberosity is common in acute cases.) PLUS
3. Objective Clinical Findings: Weak or absent abduction; may also demonstrate atrophy. AND Tenderness over rotator cuff or anterior acromial area. AND Positive impingement sign and temporary relief of pain with anesthetic injection (diagnostic injection test). PLUS
4. Imaging Clinical Findings: Conventional x-rays, AP, and true lateral or axillary view. AND MRI, ultrasound, or arthrogram shows positive evidence of deficit in rotator cuff.
(Washington, 2002)

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

***Risk versus benefit**:*
Repair of rotator cuff tears can improve pain and function for carefully selected patients, although conservative treatment has reported outcomes often equivalent to surgical management, but without surgical risks. Results following physical therapy, debridement/acromioplasty, and rotator cuff repair for symptomatic nontraumatic rotator cuff tears were similar at mid-term follow-up. One-third of rotator cuff repairs ultimately fail, 3 out of 4 within three months of surgery. The re-tear rate has been somewhat predictable based on tear size, between 10% for ≤2 cm2 up to almost 60% for >8 cm2. Surgical outcomes are much better in younger patients who are less likely to have degenerative changes. Outpatient rotator cuff repair is well-accepted and relatively cost effective. Workers' compensation status and/or diabetes predict generally worse outcomes following repair. Revision repairs are inferior to primary, having doubled failure rates at 2 years. Post-operative infection following cuff repair has been <1% overall, but higher for open approaches and male sex. Open repairs also have more than double the incidence of early complications (infection, readmission, or return to surgery) compared to arthroscopic procedures. Problematic postoperative stiffness occurs in 5% of arthroscopic repairs. *For specific research and discussion see below.*

Repair of the rotator cuff is indicated for significant tears that impair activities by causing weakness of arm elevation or rotation, particularly when acute in younger working individuals. However, rotator cuff tears are frequently only partial-thickness or smaller full-thickness tears. These present primarily as subacromial impingement, and surgery is reserved for cases failing conservative therapy for at least three months. Surgery is not indicated for patients with mild symptoms or those who have no limitations of activities. (Ejnisman-Cochrane, 2004) (Grant, 2004) Lesions of the rotator cuff are best thought of as a continuum, from mild inflammation and early degeneration to full avulsions. “Full-thickness tear”, also called complete tear, has been defined as a split of the soft tissue into two pieces, basically creating a hole in a portion or the entire tendon. “Partial-thickness tear” represents damage to the soft tissue without completely severing it. (AAOS, 2011) Partial-thickness tears are commonly described either on MRI or during arthroscopy based on a percentage of the “thickness” or depth of the tendon involved, with higher numbers representing worse tearing. Partial-thickness tearing can occur on either the articular side (undersurface) or subacromial side (outer or superior surface). As a continuum of the impingement process, eventually a hole (small full-thickness tear) can develop, most commonly at the anterior insertion of the supraspinatus. Studies of normal subjects document the universal presence of degenerative tearing including full avulsions without symptoms. Conservative treatment can have results similar to surgical treatment but without surgical risks. Studies of conservative treatment for full-thickness tears have demonstrated 82-86% success for patients presenting within three months of injury. Surgical outcomes are much better in younger patients with rotator cuff tears, than in older patients who often have degenerative changes. Surgical consultation is indicated for patients who have: Activity limitations for more than three months, plus a surgical lesion; Failure of exercise programs to increase range of motion and strength of the shoulder musculature; Clear clinical and imaging evidence of a surgically repairable lesion; Red flag conditions (e.g.,

acute cuff tear in a young working individual, glenohumeral joint dislocation, etc.). Proven acute traumatic tears of the rotator cuff in young workers may be surgically repaired acutely to restore function; in older workers, most of these tears are treated conservatively at first. Partial-thickness tears are treated the same as impingement syndrome regardless of MRI findings. Outpatient rotator cuff repair is a well-accepted and cost effective procedure. (Cordasco, 2000) There continues to be significant variation in surgical decision-making and a lack of clinical agreement among orthopedic surgeons about indications for rotator cuff surgery. (Dunn, 2005) For rotator cuff pain with an intact tendon, a trial of 3 to 6 months of conservative therapy is reasonable before orthopedic referral. Patients with small tears of the rotator cuff may be referred to an orthopedist after 6 to 12 weeks of conservative treatment. (Burbank2, 2008) Patients with workers' compensation claims have worse outcomes after rotator cuff repair. (Henn, 2008)

Revision rotator cuff repair: The results of revision rotator cuff repair are inferior to those of primary repair. While pain relief may be achieved in most patients, selection criteria should include patients with an intact deltoid origin, good-quality rotator cuff tissue, preoperative elevation above the horizontal, and only one prior procedure. (Djurasovic, 2001) Although revision rotator cuff repair had similar short-term outcomes with primary surgery, by 2 years symptomatic re-tearing was twice as likely. (Shamsudin, 2015)

Recent research: Evidence regarding various operative and nonoperative treatments for rotator cuff tears is limited and inconclusive according to an AHRQ comparative effectiveness review. While the data are sparse, patients improved substantially with all interventions; there were few clinically important differences between approaches, and complications were relatively rare. Most patients try a course of physical therapy before considering surgery, but there has been very little good quality research to guide the type or timing of nonoperative treatment, or who might best benefit from various forms of treatment. Four of five studies comparing surgical and nonsurgical management favored operative repair, but the evidence was too limited to make conclusions regarding comparative effectiveness. 113 studies comparing various operations found little difference in functional outcomes between open vs mini-open repair, mini-open vs arthroscopic repair, arthroscopic repairs with vs without acromioplasty, and single-row vs double-row fixation. Adding continuous passive motion to postoperative physical therapy does not appear to be helpful; 11 trials showed moderate evidence for no difference in function or pain. In general, most studies found no difference in health-related quality of life, function, pain, range of motion, and strength with one therapy approach versus another (e.g., with or without aquatics, individualized vs at home, videotape vs therapist-based, etc.). In 72 studies assessing prognostic factors, older age, increasing tear size, and worse preoperative symptoms were consistently associated with recurrent tears; whereas gender, workers' compensation status, and duration of symptoms was not generally predictive of poorer outcomes. (Seida, 2010)

A prospective cohort study concluded that PT is effective for most patients with atraumatic full-thickness rotator cuff tears and shoulder pain, without a need for surgery. By six weeks fewer than 10% of patients had elected surgery; and at 2 years only 2% of those remaining had subsequently opted for surgery. (Kuhn, 2011) One-third of rotator cuff repairs re-tear, with 74% of the failures occurring within three months of surgery. Healed tendons at six months are predictive of good outcomes at seven years. (Kluger, 2011) Not surprisingly, larger tears are more difficult to successfully repair. The re-tear rate based on rotator cuff tear size is: 10% for ≤2 cm2; 16% for 2–4 cm2; 31% for 4–6 cm2; 50% for 6–8 cm2; & 57% for >8 cm2 (Murrell, 2012) There is insufficient evidence to suggest comparative efficacy for operative vs nonoperative treatment of rotator cuff tears in in patients aged older than 60 years. (Downie, 2012) An RCT showed that full-thickness rotator cuff repair outcomes were the same, with or without acromioplasty. Acromioplasty is often added at the time of arthroscopic cuff repair, but it does not necessarily improve outcomes at 2-years. (Abrams, 2014) Non-contrast MRI is sufficient for rotator cuff tear diagnosis. (Spencer, 2013) (Farshad-Amacker, 2013) (Arnold, 2012) (Major, 2011) Conservative treatment is a good option for the initial treatment of isolated, symptomatic, nontraumatic, supraspinatus tears in older patients. An RCT comparing the effectiveness of physical therapy, acromioplasty, and rotator cuff repair for the treatment of symptomatic nontraumatic rotator cuff tears (RCTs) found no significant difference in clinical outcomes among the differing interventions at 2-years. (Kukkonen, 2015) Post-operative infection rates for 1,824 rotator cuff repairs (open, mini-open, and arthroscopic) was 0.77% overall, but significantly lower for both arthroscopic approach and female sex. (Vopat, 2016) A population analysis involving 175,000 patients with 1/3 being diabetic, noted both cuff repair incidence and surgical hazard ratios to be 33% higher among diabetes, showing this disease to be an independent negative risk factor. (Huang, 2016) Significantly lower early complications (infection, readmission, or return to surgery) were reported among veterans undergoing arthroscopic (0.9%) vs. open repairs (2.1%). (Owens, 2015) An incidence of problematic postoperative stiffness was noted in about 5% of arthroscopic repairs, with this problem being relatively higher for calcific

tendinitis, age under XX, and worker's compensation status. (Huberty, 2009)

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**